the draft Call Letter, we intend to conduct outlier checks during our annual formulary review process and will share information with sponsors, so that sponsors may determine if they wish to submit a PA for approval or continue ensuring Part D coverage through other means, such as retrospective review. There has also been confusion from plan sponsors about how such edits are appropriately used during transition periods. Section 30.4.8 of Chapter 6 of the Prescription Drug Benefit Manual (available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf) discusses edits for transition fills.

The requirements to verify payment for Part D uses, maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and establish quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use apply regardless of the transitional status of an enrollee's medication(s). In other words, such POS PA edits are appropriate, even during transition.

In particular, some sponsors have interpreted the section 30.4.8 language, "Drug utilization management edits that are appropriate during a beneficiary's transition period include … edits to prevent coverage of non-Part D drugs (i.e., excluded drugs)" to mean that excluded drugs[8] is the only condition for which they should implement POS PA during transition pursuant to this criterion. This is incorrect. Drug utilization management edits to prevent coverage of non-Part D drugs include those which prevent coverage of a formulary drug that is being dispensed for an indication that is not medically accepted. Because our clarified guidance of this criterion is focused on those drugs that pose the greatest risk for non-Part D-covered indications, CMS would not expect to see excessive use of POS PA edits during transition for drugs as a result of this clarified guidance.

With respect to EGWPs and this section of the Call Letter, we recognize that EGWPs may not want to implement prior authorization edits to determine whether a drug is a Part D covered drug, if they cover non-Part D covered drugs under supplemental non-Medicare benefits. However, in this situation, we remind sponsors that they are responsible for determining whether a drug is a Part D covered drug before submitting a PDE to CMS. In addition, we note that brand drugs that are not Part D covered drugs are not eligible for the 50% manufacturer discount, and EGWPs must have a mechanism to ensure the discount is not applied once the determination has been made that a brand drug is not a covered Part D drug.

[8] A drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act.